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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,623	03/10/2004	Edward I. Wulfman	89000.3013NP	6167

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EXAMINER	
WEBB, SARAH K	
ART UNIT	PAPER NUMBER
3731	
MAIL DATE	DELIVERY MODE
10/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,623	WULFMAN ET AL.	
	Examiner	Art Unit	
	SARAH WEBB	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,10,16,17 and 19-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,10,16,17 and 19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the appeal brief filed on 8/4/2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final)or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37.

The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below (please see the last page).

Response to Arguments

2. Applicant's arguments with respect to the rejections of claims 2-5, 10, 16, 17, 19-27 by combinations of Zacca et al. have been considered but are moot in view of the new ground(s) of rejection.

3. On pages 15 and 16 of the Appeal Brief filed 8/4/2010, Applicant argues that Mische does not disclose a liquid flood space. These arguments are not persuasive. The language *"to form a liquid flood space between the liner and the torque tube"* is a functional recitation and not given full patentable weight. Liquid is *capable of* permeating the spaces between the coils of the torque tube (94) (see description of torque tube construction at column 10, lines 53-55) and the liner (100), which forms a "flood space" or "liquid seal", as defined in Applicant's specification. The claims do not specify any further structural requirements of the flood space, so the Mische device is considered to meet the requirement since it includes all the structural requirements and is *capable of* performing the recited function.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19 and the claims dependent from claim 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase *"infusion port supplying liquid to the liquid seal assembly"* renders the claim indefinite,

because the liquid seal assembly is not defined beforehand. The preamble merely states that the catheter includes a liquid seal assembly but fails to specify the structures included in this component or its relationship to the other components. Therefore, it is unclear how the infusion port is related to the other claimed features.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2-5, 10, 16, 17, 19-21, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,490,859 (Mische et al.).

Mische discloses an aspirating catheter device that includes all the claimed components of the catheter with a liquid sealing assembly. In claim 19, the language *"uses liquid as a sealing medium to prevent air or other fluids from contacting moveable catheter components in the area of a proximal end of a torque tube"* is a functional recitation that is not given full patentable weight. In claim 20, the language *"whereby during operation of the medical device, liquid enters the flood space…"* is another functional recitation that is not given full patentable weight. As long as the prior art device discloses all the structural features and is *capable of* performing the recited function, it is considered to meet the claim requirements.

The Mische device includes a torque tube (94) rotated by a drive system (24) and a liner (100) surrounding the torque tube (94) (see cutaway in Figure 4). The liner (100) extends to the proximal end of the torque tube (92), where the proximal ends of both tubes are positioned within a hand-held housing (12) (shown in cut-out of Figure 12). The proximal handle also includes a "sealing site" defined by seals (84 and 86) that are located near aspiration/ infusion ports (80, 82). As more clearly shown in Figures 6 and 7, the liner (100) does not extend the full length of the torque tube (94), as it terminates proximal to the working head at an "intersect area" (proximal to element 104). The catheter assembly includes an infusion port (80) that is *capable of* supplying liquid to the torque tube and liner's lumen (column 10, lines 18-23). Since the port is open to the atmosphere, the liquid is supplies at atmospheric pressure. The aspiration catheter further includes a catheter (90) surrounding the liner (100) so that an aspiration lumen is formed between these two components and is in communication with an aspiration port (82) (column 10, lines 31-40). The catheter (90) extends proximally to the sealing and aspiration site that includes the ports (80, 82) and seals (84,86) (column 10, lines 46-47) and distally beyond the "intersect area", or the termination point of the liner. This configuration allows liquid exiting the liner (100) at the "intersect area" to be *capable of* directly entering the aspiration lumen.

The language *"to form a liquid flood space between the liner and the torque tube"* is a functional recitation and not given full patentable weight. Liquid is able to enter the lumen defined by the torque tube and the liner from either the working head or the infusion port (80) at the proximal end of the device (column 10, lines 12-47). This liquid

is *capable of* permeating the spaces between the coils of the torque tube (see description of torque tube construction at column 10, lines 53-55) and the liner (100), which forms a "flood space" or "liquid seal", as defined in Applicant's specification. The Mische device includes all the structural requirements and is capable of performing the recited function, so it meets the claim requirements.

Regarding claim 2, an embodiment in Figure 12 shows that the "flood space" can include a clearance area between the liner (100) and the torque tube (94).

Regarding claim 3, the torque tube is a coiled drive shaft (92) (column 10, lines 50-65) and the "flood space" includes gaps between the coils.

Regarding claim 4, the torque tube includes a lumen for passage of guidewire (42) and this lumen can also function as part of the "flood space."

Regarding claim 5, Mische includes a suction port (82) for aspirating fluid from a lumen, as discussed above. The recitation of the relative pressure in the "flood space" during operation of the device is a recitation of the intended use of the device, which is not given patentable weight. Since the device is capable of being connected to a source of suction for aspiration, it is capable of having a lower pressure in the flood space relative to the surrounding areas during operation.

Regarding claim 10, the sealing assembly includes two ports, so one of the ports is capable of acting as an overflow port for exit of excess liquid. The torque tube (94) extends through both ports (80, 82) and includes an opening (88) that is also capable of functioning as an overflow port for exit of excess liquid.

Claim 21 recites functional language directed towards the intended use of the device. The device is *capable of* achieving a lower pressure at its distal end due to the negative pressure induced by aspiration of the treatment site.

Regarding claim 24, the liner (100) is formed of a thin fluoropolymer tubing (column 11, lines 25-30). This type of material is considered to meet the requirements of a thin, tough, and flexible polymer material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mische et al.

Regarding claim 22, Mische explains that the drive shaft coil (94) should have an outer diameter of about 0.025 inch (col. 5, lines 60-65), but fails to disclose the inner diameter of the liner. Since the liner surrounds the drive shaft coil (94) and its inner diameter closely approximates the outer diameter of the drive shaft, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the liner to have an inner diameter of about 0.03-0.04 inch, as a mere change in size of a component is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claim 23, Micshe is silent with respect to the length of the liner, but does state that the catheter's length can be 133 cm (column 10, lines 43-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the liner to have a length similar to the length of the catheter, which is greater than about 6 inches, as a mere change in size of a component is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mische et al. in view of Milo (US 6,258,052).

Mische forms the liner (100) from a fluoropolymer that provides a lubricious surface, but fails to form the liner of polyimide tubing with a lubricious coating. Milo teaches that forming a liner over a coiled shaft from a polyimide tube increases pushability and column strength (col. 2, In. 61 - col. 3, In. 2). It would have been obvious to one of ordinary skill to include a polyimide material with the lubricious liner of Mische, as Milo teaches that this increases the pushability and column strength of the device. Additionally, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mische et al. in view of US 5,938,670 (Keith et al.).

Mische fails to explicitly explain that the fluid flow rate in the flood space is reduced in the proximal to distal direction. Mische does teach that the location that

fluid exits the liner (100), or the "intersect area", is predetermined by appropriately choosing the length of the liner (100) (col. 25, In. 32-36). Keith teaches that a smaller gap provides more resistance to fluid flow and therefore reduces pressure within a flood space along the length of a liner in a distal direction during the operation of the device in order to prevent significant fluid loss and provide effective cooling of a drive shaft (col. 12, In. 11-34). In light of Keith's teachings, it would have been obvious to one of ordinary skill in the art to optimize the dimensions of the Mische liner to provide more resistance to fluid flow, but it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH WEBB whose telephone number is (571) 272-5749. The examiner can normally be reached on 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. W./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
10/23/2010